OIPE IAP90 JUL 31 2006 PATENT & TRADEMARK OFFICE

IFW

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Kunio YASUNAGA, et al.

Docket No: Q89135

Appln. No.: 10/551,964

Group Art Unit: 1644

Confirmation No.: 3948

Examiner: NOT YET ASSIGNED

Filed: October 5, 2005

For: METHOD OF SCREENING ANTIOBESITY AGENTS AND ANIMAL MODEL OF OBESITY

LETTER

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Information Disclosure Statement filed March 8, 2006, for the convenience of the Examiner, Applicant is now able to provide, and attaches hereto, a copy of an English translation of the International Preliminary Report on Patentability (IPRP).

No additional cited art documents are submitted or listed herewith, since the two (2) documents cited in the IPRP were previously cited and listed in the Information Disclosure Statement filed March 8, 2006.

Respectfully submitted,

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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: July 31, 2006

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
YK0417PCT711		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/007692	03.06.2004	06.06.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant		
ASTELLAS PHARMA INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      1 disk , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/007692

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished.

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
   - ☐ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☒ neither restricted the claims nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
   - ☐ complied with.
   - ☒ not complied with for the following reasons:

The group of inventions that is set forth in claims 1 to 6 (invention group A) includes inventions that are related to the angiopoietin-related growth factor. Meanwhile, the invention that is set forth in claim 7 (invention B) is related to non-human knockout animals in which the gene that codes the angiopoietin-related growth factor has been deleted, and the invention that is set forth in claim 8 (invention C) is related to non-human transgenic mice that are capable of expressing the angiopoietin-related growth factor.

Invention Group A and Invention B

It is apparent that there is no technical relationship involving one or more of the same or corresponding special technical features among invention group A and invention B.

[Refer to the Supplemental Box]

4. Consequently, this report has been established in respect of the following parts of the international application:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. 1-6

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	5, 6	YES
	Claims	1-4	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 2000-300263 A (Helix Research Institute), 31 October 2000, entire text (Family: none)

Document 2: WO 99/15653 A1 (GENENTECH, INC.), 01 April 1999, entire text & EP 10155585 A2 & JP 2001-517437 A

Claims 1 to 4

The inventions set forth in claims 1 to 4 do not involve an inventive step in the light of the inventions that are disclosed in documents 1 and 2 cited in the international search report.

Documents 1 and 2 can be considered to disclose the gene that codes the angiopoietin-related growth factor in humans along with the base sequence thereof. In addition, it was common technical knowledge prior to the priority date of the present application that in cases when a given gene is well known, it is possible to acquire the promoter of said gene by means of genetic engineering techniques.

Therefore, it would have been easy for a person skilled in the art to conceive of attempting to acquire the promoter of the gene that codes the human angiopoietin-related growth factor by means of a genetic

engineering technique which employs probes and/or primers that have been created based on the base sequences that are disclosed in documents 1 and 2. At that time, a person skilled in the art could have searched upstream from the gene that codes the human angiopoietin-related growth factor in order to acquire DNA fragments that exhibit a high promoter activity, as appropriate.

In addition, a person skilled in the art could produce a recombinant vector comprising a promoter that has been obtained in this manner, and could produce a transformant comprising said recombinant vector, as appropriate.

Furthermore, there cannot be considered to be any especially significant effects that result from employing the configurations of the inventions that are set forth in claims 1 to 4 of the present application.

Claims 5 and 6

The inventions set forth in claims 5 and 6 are not disclosed in any of the documents that are cited in the international search report, and would not have been obvious to a person skilled in the art.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purposes of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* *If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box IV

Invention Group A and Invention C

It is apparent that there is no technical relationship involving one or more of the same or corresponding special technical features among invention group A and invention C.

Invention B and Invention C

Invention B and invention C share the common feature of being inventions which are related to the "angiopoietin-related growth factor that is set forth in the present application." However, the angiopoietin-related growth factor that is set forth in the present application was well known prior to the priority date of the present application (if necessary, refer to the documents JP 2000-300263 A, WO 99/15653 A1 and the like); therefore, there cannot be considered to be a technical relationship involving one or more of the same or corresponding special technical features among invention B and invention C.

As a result, the inventions that are set forth in claims 1 to 8 do not conform to the requirement of unity of invention.

However, the inventions that are set forth in claims 1 to 6 can be considered to conform to the requirement of unity of invention.